UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
ADDRESS: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/834,309	04/11/2001	Xiaojiang Chen	2848-43	3032

22442 7590 12/18/2002

SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER, CO 80202

EXAMINER
ZHOU, SHUBO

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/18/2002

/3

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
09/834,309	CHEN
Examiner	**Art Unit**
Shubo "Joe" Zhou	1631

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *8-15,17-23 and 25-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,16 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 September 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Applicants' elections, with traverse, of Group I (claims 1-27), of species I-A (claims 3-7), directed to candidate compounds inhibiting the binding of CR2 to its ligands, of species I-5 (claim 16), and of I-a (claim 24), in Paper No. 11, filed 9/13/02, are acknowledged.

The traversal is on the ground(s) that there would be no undue search burden if Groups I-IV and VI were co-examined. See page 3 of Paper #11. This is not found persuasive because as set forth in the previous Office action, the inventions of Groups I-VI are directed to distinct computational methods of drug design using three dimensional structure of CR2. The distinct methods have different functions, modes of operations and can produce different results. Further, these distinct methods are often characterized and published separately. Co-examination of the methods would require searching the distinct inventions in both patent and non-patent literature with distinct search strategies, and thus would certainly impose undue search burden to the Office. The requirement is still deemed proper and is therefore made FINAL.

In light of applicants' species election in Group I, genus claims 1-2, and species claims 3-7, 16 and 24 are elected. Thus, claims 1-47 are currently pending, but only claims 1-7, 16 and 24 are under consideration.

Claims 8-15, 17-23, and 25-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention or species, there being no allowable generic or linking claim.

Specification

The specification is objected to because of the following:

The section of "Brief Description of the Drawings" in the specification refers to Fig. 2A through Fig. 2E, Fig. 3A through Fig. 3F. However, the drawings submitted only contain Fig. 2 and Fig. 3.

Appropriate correction is required.

Claim Rejections-35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 16 and 24 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "potentially bind to" CR2 in claim 1 and all its dependent claims is vague and indefinite. It's unclear how much potential is required in the claim for something to bind to CR2. Thus, the metes and bounds of the claims are unclear.

Claim Rejections-35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mond et al. (US patent No. 6,432,679, date of patent: Aug. 13, 2002, date of filing: Jun. 10, 1999) in view of Prodinger et al. (IDS document : J. Immunol. Vol. 161 : 4604-4610, 1998), and further in view of Hampton Research.

Mond et al. disclose vaccine adjuvants that bind to the CR2 complex containing EBV Gp350/220 which is known to bind to CR2. See columns 2-3. In addition, Mond et al. disclose a method for identifying Gp350/220 analogs that may bind to CR2 and inhibit its binding to CR2's natural ligands using rational drug design. The method comprises "the steps of determining the three-dimensional structure of that portion of the CR2 polypeptide which binds to Gp350/220, analyzing the three-dimensional structure for likely binding site of Gp350/220 or the C3b peptide, synthesizing a molecule that is predicted to bind to a predicative site, and determining the binding and adjuvanting activity of the molecule". See column 7, lines 20-29.

However, Mond et al. do not disclose the three-dimensional structure of CR2 short consensus repeat (SCR) 1-2 region, which structure is defined by atomic coordinates, as required in the instant claims.

Prodinger et al. characterize an monoclonal antibody that binds to CR2 and interferes the binding of CR2 to its ligand, C3dg, and determine that C3dg binds to a recess formed between the short consensus repeats 1 and 2 of CR2, underscoring the importance of the region in ligand binding. See page 4604.

In light of the disclosure by Mond et al., one of ordinary skill in the art would have been motivated to crystallize the short consensus repeats 1 and 2 of CR2 for identifying compounds that would inhibit the binding of CR2 to its ligands, such as Gp350/220 and C3dg, by rational drug design as proposed by Mond et al.

There would have been a reasonable expectation of success for such a crystal because protein crystallization would have become routine in the field. For instance, Hampton Research provided a crystal screening kit, Crystal Screen, before 1998 for routine crystallization (while the exact date of the commercial availability of the kit to the public is unknown, it should be before 1998 because Khurana et al. (Proc. Natl. Acad. Sci, Vol. 95, pages 6768-6773, June 1998) disclose using such a kit for the crystallization of a reductase. See page 6769, left column. The Crystal Kit is a complete reagent kit designed to provide a rapid screening method for the crystallization of biological macromolecules and it provides a detailed procedure and all the reagents needed. See the "User Guide" for the kit. At least 107 macromolecules have been crystallized with the assistance of Crystal Screen including human IFN-gamma receptor, as disclosed by Hampton Research's 2002 Catalog. See page 5 and 7 of the Catalog. This provides evidence for the general applicability of the kit for the crystallization of a variety of different proteins.

Claims 1-7, 16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mohammadi et al. (WO 98/07835, 2/26/1998).

The claims are drawn to a method of performing a computer analysis of using the structural coordinates to identify an agent that potentially binds to CR2 protein.

In addition to disclosing the crystal structure of a protein tyrosine kinase, Mohammadi et al. shows in the abstract and throughout a method of performing a computer analysis of using the structural coordinates of the protein kinase to identify an agent that binds to and modulate the protein tyrosine kinase. See the abstract, lines 10-17of page 4. Such a modulator can activate or inhibit the catalytic activity of the protein tyrosine kinase. See page 11, lines 5-25. Mohammadi et al. also disclose that these modulators are identified by docking a computer representation of a structure of a protein tyrosine kinase with or without a compound binding to, which structure is defined by structural coordinates. See pages 29-35.

The computational process of identifying modulators by Mohammadi et al. differs from the claimed invention only in the content of the crystal coordinates. The MPEP states in 2106 section VI in discussing computer related inventions in light of In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983):

VI. DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH 35 U.S.C. 102 AND 103

As is the case for inventions in any field of technology, assessment of a claimed computer-related invention for compliance with 35 U.S.C. 102 and 103 begins with a comparison of the claimed subject matter to what is known in the prior art. If no differences are found between the claimed invention and the prior art, the claimed invention lacks novelty and is to be

rejected by Office personnel under 35 U.S.C. 102. Once distinctions are identified between the claimed invention and the prior art, those distinctions must be assessed and resolved in light of the knowledge possessed by a person of ordinary skill in the art. Against this backdrop, one must determine whether the invention would have been obvious at the time the invention was made. If not, the claimed invention satisfies 35 U.S.C. 103. Factors and considerations dictated by law governing 35 U.S.C. 103 apply without modification to computer-related inventions. If the difference between the prior art and the claimed invention is limited to descriptive material stored on or employed by a machine, Office personnel must determine whether the descriptive material is functional descriptive material or nonfunctional descriptive material, as described supra in sections IV.B.1(a) and IV. B.1(b). Functional descriptive material is a limitation in the claim and must be considered and addressed in assessing patentability under 35 U.S.C. 103. Thus, a rejection of the claim as a whole under 35 U.S.C. 103 is inappropriate unless the functional descriptive material would have been suggested by the prior art. > In re Dembiczak, 175 F.3d 994, 1000, 50 USPQ2d 1614, 1618 (Fed. Cir. 1999).< Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. Cf. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed Cir 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

Common situations involving nonfunctional descriptive material are:

a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium.

- a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer). or

- a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

Thus, if the prior art suggests storing a song on a disk, merely choosing a particular song to store on the disk would be presumed to be well within the level of ordinary skill in the art at the time the invention was made. The difference between the prior art and the claimed invention is simply a rearrangement of nonfunctional descriptive material.

The difference between Mohammadi et al. and the claimed invention constitutes non-functional descriptive material because the content of the structure coordinates of a protein or protein complex does not alter how the computational method functions, i.e., the structural coordinates of the protein does not limit the claimed method to perform different steps than the method of Mohammadi et al. Therefore no patentable weight is given to the structural coordinates of the protein in the claimed method.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is 703)-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D.

Patent Examiner

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600